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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,079	02/16/2000	Joni Kristin Doherty	49321-1A	5713

7590 01/29/2003

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EXAMINER
HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/506,079	DOHERTY ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *4-7,11-17 and 21-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,8-10 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. In view of the papers filed July 23, 2001 (Paper No. 11), it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the deletion of Joni Kristin Doherty as a co-inventor, and the addition of Adam Evans and William D. Henner as co-inventors.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

2. Claims 4-7, 11-17 and 21-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected without traverse, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 19.

Claims 1-37 are pending.

Claims 4-7, 11-17 and 21-37, drawn to non-elected inventions, are withdrawn from consideration.

Claims 1-3, 8-10, and 18-20 are examined on the merits.

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claims 9 and 10 are objected to for depending from claim 6, which has been withdrawn from consideration.

Claim Rejections - 35 USC § 112

4. Claims 1-3, 9, 10 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and 18 are indefinite for reciting a level of affinity without reciting the units.

Claims 9 and 10 are indefinite because they are set forth as dependent from claim 6, which is drawn to a polynucleotide.

Claims 3 and 10 contains the trademark Herceptin. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark cannot be used properly to identify any particular material or product. A trademark is used to identify a source of goods, and not the goods themselves. Thus, a trademark does not identify or describe the goods associated with the trademark or trade name. In the present case, the

trademark is used to identify a monoclonal antibody that has a particular binding site on the extracellular domain and, accordingly, the identification is indefinite.

5. Claims 1-3, 8-10 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The basis for this rejection is that the disclosure of the specification fails to describe the genus of compounds encompassed by the claims.

Claims 1-3, 9 and 10 are drawn to polypeptides comprising from about 50-79 amino acids taken from the sequence of SEQ ID NO: 1. Claims 18-20 are drawn to pharmaceutical compositions comprising agents that include polypeptides of the same scope as that of claim 1. The claims fail to recite that the 50-79 amino acids form a contiguous amino acid sequence, and are broadly interpreted to read on any polypeptide with a length of at least 50 amino acids, which 50 amino acids happen to occur somewhere, and in any order, in the sequence of SEQ ID NO: 1, where the polypeptide binds to the extracellular domain of HER-2 at an affinity of at least 10^8. SEQ ID NO: 1, which consists of 79 amino acids but also may be substituted at 9 sites with more than one amino acid (8 out the 9 have two choices, and 1 out of the 9 has 4 choices), is not representative of the genus of molecules encompassed by the claims, because the claims read on polypeptides with very little structural definition and only a functional limitation.

Claim 8 are drawn to polypeptides comprising from about 300 to 419 amino acids taken from the sequence of SEQ ID NO: 2, wherein the C terminal 79 amino acids are present, and

wherein at least three N-linked glycosylation sites are present. Claim 18 is drawn to pharmaceutical compositions comprising agents that include polypeptides of similar scope as that of claim 8, except that the polypeptides may comprise from about 80 to 419 amino acids form SEQ ID NO: 2. The claims fail to recite that the 300 to 419 (or 80 to 419) amino acids form a contiguous amino acid sequence, and are broadly interpreted to read on any polypeptide with a length of at least 300 amino acids (or 80 for claim 18), of which 79 happen to occur somewhere in the C terminal end of SEQ ID NO: 2, and the claimed polypeptide may comprise these amino acids in any order, and the rest of the polypeptide comprises amino acids (121 amino acids or 1 for claim 18) that happen to occur somewhere in the N terminal end of SEQ I D NO: 2, and the claimed polypeptide may comprise these amino acids in any order. SEQ ID NO: 2, which consists of 419 amino acids, but also may be substituted at 10 sites with more than one amino acid (9 out of the 10 have two choices, and 1 out of the 2 the 10 has 4 choices), is not representative of the genus of molecules encompassed by claim 8 or of the pharmaceutical composition of claim 18.

Although the sequences represented by SEQ ID NOS: 1 and 2 are not limited to one sequence each, because of the possible substitutions, the number of sequences that are defined by SEQ ID NOS: 1 and 2 are very small in comparison to the large genus encompassed by the claims because the order of the amino acids is not recited. Applicant may obviate this rejection by amending the claims to recite that the claimed polypeptides and pharmaceutical compositions comprise contiguous amino acid sequences from SEQ ID NO: 1 or SEQ ID NO: 2.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. The instant application does not receive benefit of the filing date of the parent application, 09/234,208, because support for the genus of polypeptides that are encompassed by SEQ ID NO: 1 and SEQ ID NO: 2 cannot be found in parent application 09/234,208. The parent application disclosed species of polypeptides that fall within the genus encompassed by each of SEQ ID NO: 1 and SEQ ID NO: 2. However, the parent application lacks description of the genus, because the parent application lacks description of sites that may be substituted with alternate amino acids. Thus, for the purposes of comparison with the prior art, the filing date of the instant application 2/16/2000 is used.

7. Claims 1-3, 8-10 and 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Doherty et al (U.S. Patent 6,414,130; issued July 2, 2002; effective filing date of Jan. 20, 1999).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C.

102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Doherty discloses polypeptides comprising SEQ ID NO: 1 or SEQ ID NO: 2, where the SEQ ID NO: 1 or SEQ ID NO: 2 of Doherty are species of the SEQ ID NO: 1 or SEQ ID NO: 2 of the instant application (see abstract and col. 2, lines 41-50, col. 3, lines 1-12, col. 3 line 52 – col. 4, line 5; sequence listing, col. 19-col. 25). Thus, Doherty discloses the claimed inventions.

8. Claims 1-3 and 8-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Doherty et al (Doherty et al, Proc. Nat. Acad. Sci., USA, 96(19): 10869-10874, 1999, Sep.)

Doherty(PNAS) teaches Herstatin, which is a sequence that comprises 79 amino acids of SEQ ID NO: 1 and 300 amino acids of SEQ ID NO: 2. Doherty(PNAS) teaches that Herstatin may be glycosylated. Thus, Doherty(PNAS) teaches the claimed inventions.

9. Claims 1, 3, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Greene et al (U.S. Patent 5,464,751; issued Nov. 7, 1995).

Claims 1, 3, 18 and 19 are broadly interpreted to read on polypeptides that bind to Her-2 (p185). The affinity of binding of the claimed polynucleotides is unknown, because the claims fail to recite units. Claim 3 is drawn to a polypeptide that binds to Her-2 at a site different from the site of the monoclonal antibody 4D5 (referred to as Herceptin® in the claims). Claim 18 and 19 are interpreted to be drawn to polypeptides with an intended use of therapy of solid tumors

that overexpress HER-2. The broad interpretation is based on the fact that the claims recite that the amino acids may be taken from SEQ ID NO: 1 or SEQ ID NO: 2, and fail to recite that the amino acids are a contiguous portion of SEQ ID NO: 1 or SEQ ID NO: 2. Furthermore, the claims recite "having", which is interpreted as open language. Thus, the polypeptides may be any size with a minimum size of 50 amino acids.

Greene teaches NAF which is a proteinacious substance that binds the extracellular domain of p185 (also known as HER-2) (see col. 3, lines 18-26; col. 15, line 64 – col. 16, line 35). Absent evidence to the contrary, it appears that NAF binds to a site different from that of the monoclonal antibody 4D5 because NAF activates that function of p185, whereas 4D5 inhibits the function of p185. Greene discloses pharmaceutical compositions of NAF (see col. 6, lines 44- col. 7, line 18). Thus, Green discloses the claimed inventions. This rejection would be overcome if the claims were amended to recite that the amino acids derived from SEQ ID NO:1 or SEQ ID NO: 2 were a contiguous segment.

10. Claims 1, 3, 10, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Wels et al (U.S. Patent 5,571,894; issued Nov. 5, 1996).

Claims 1, 3, 10, 18 and 19 are broadly interpreted to read on polypeptides that bind to Her-2 (p185). The affinity of binding of the claimed polynucleotides is unknown, because the claims fail to recite units. Claims 3 and 10 are drawn to polypeptides that bind to Her-2 at a site different from the site of the monoclonal antibody 4D5 (referred to as Herceptin® in the claims). Claim 10 is drawn to glycosylated polypeptides. Claim 18 and 19 are interpreted to be drawn to polypeptides with an intended use of therapy of solid tumors that overexpress HER-2. The broad

interpretation is based on the fact that the claims recite that the amino acids may be taken from SEQ ID NO: 1 or SEQ ID NO: 2, and fail to recite that the amino acids are a contiguous portion of SEQ ID NO: 1 or SEQ ID NO: 2. Furthermore, the claims recite "having", which is interpreted as open language. Thus, the polypeptides may be any size with a minimum size of 50 amino acids.

Wels teaches recombinant antibodies that bind to the extracellular domain of e-erbB-2 (also known as Her-2). The recombinant antibodies may be expressed in mammalian cells, which would result in glycosylated antibodies. One embodiment taught by Wells is SEQ ID NO: 11, which has 4 asparagine residues, and thus, 4 possible sites of glycosylation (see col. 15, lines 17-28; col. 41, lines 7-10; col. 25, lines 54- col. 26, lines 56). Absent evidence to the contrary, the antibodies taught by Wels bind to sites different from the binding site of the monoclonal antibody 4D5. Wels discloses pharmaceutical compositions (col. 22, line 52 – col. 23, line 9) Thus, Wels discloses the claimed inventions. This rejection would be overcome if the claims were amended to recite that the amino acids derived from SEQ ID NO:1 or SEQ ID NO: 2 were a contiguous segment.

11. Claims 1, 3, 8, 10, 18 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Ring (U.S. Patent 6,054,561; issued Apr. 25, 2000; filing date June 7, 1995).

Claims 1, 3, 8, 10, 18 and 19 are broadly interpreted to read on polypeptides that bind to Her-2 (p185). The polypeptides of claims 8 and 10 are glycosylated. Claims 3 and 10 are drawn to polypeptides that bind to Her-2 at a site different from the site of the monoclonal

antibody 4D5 (referred to as Herceptin® in the claims). Claim 18 and 19 are interpreted to be drawn to polypeptides with an intended use of therapy of solid tumors that overexpress HER-2. The broad interpretation is based on the fact that the claims recite that the amino acids may be taken from SEQ ID NO: 1 or SEQ ID NO: 2, and fail to recite that the amino acids are a contiguous portion of SEQ ID NO: 1 or SEQ ID NO: 2. Furthermore, the claims recite "having", which is interpreted as open language. Thus, the polypeptides may be any size with a minimum size of 50 amino acids for claims 1, 3, 10, 18 and 19, and a minimum size of 300 amino acids for claim 8. Claims 1, 3, 8, 10, 18 and 19 are interpreted to read on antibodies that bind to Her-2, because antibodies are polypeptides with at least 300 amino acids, and because of the lack of structural definition in the claims.

Ring discloses antibodies that bind c-erbB-2 (see claims). Absent evidence to the contrary these antibodies bind to a site different from that of the monoclonal antibody 4D5. Thus, Ring disclose the claimed inventions. This rejection would be overcome if the claims were amended to recite that the amino acids derived from SEQ ID NO:1 or SEQ ID NO: 2 were a contiguous segment.

12. Claim 18 is rejected under 35 U.S.C. 102(e) as being anticipated by Hudziak (U.S. Patent 6,399,063; issued June 4, 2002; effective filing date Jan. 25, 1988).

Claim 18 recites pharmaceutical compositions that comprise an agent that is a monoclonal antibody that binds to the extracellular domain of Her-2 in combination with at least a second agent. Hudziak discloses pharmaceutical compositions comprising an antibody to Her-2 and a second agent, such as a cytokine (TNF-alpha, TNF-beta, IL-2, IL-2, Interferon-gamma;

see col. 7, lines 3 – 61; claims 8-13). Thus, Hudziak discloses the claimed pharmaceutical compositions.

Drawings

13. New corrected drawings are required in this application because of the objections by the draftsman noted on PTO-948. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. Please note that the requirement for corrected drawings will not be held in abeyance.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-3, 8-10 and 18-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 8-10 and 18-22 of copending Application No. 09/234,208. Although the conflicting claims are not

identical, they are not patentably distinct from each other because the claims of copending application no. 09/234,208 are drawn peptides and compositions that are within the scope of the claims 1-3, 8-10 and 18-20.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
January 25, 2003

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